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185 10

08/01/90

☒ This application has been examined ☒ Responsive to communication filed on 4-27-90 ☐ This action is made final.

A shortened statutory period for response to this action is set to expire 3 month(s), ____ days from the date of this letter.
Failure to respond within the period for response will cause the application to become abandoned. 35 U.S.C. 133

Part I THE FOLLOWING ATTACHMENT(S) ARE PART OF THIS ACTION:

1. ☒ Notice of References Cited by Examiner, PTO-892.
2. ☐ Notice re Patent Drawing, PTO-948.
3. ☐ Notice of Art Cited by Applicant, PTO-1449.
4. ☐ Notice of Informal Patent Application, Form PTO-152.
5. ☐ Information on How to Effect Drawing Changes, PTO-1474.
6. ☐ _____

Part II SUMMARY OF ACTION

1. ☒ Claims 1-56 are pending in the application.
   Of the above, claims 0 are withdrawn from consideration.
2. ☐ Claims 15-23, 35-37 have been cancelled.
3. ☐ Claims _____ are allowed.
4. ☒ Claims 1-14, 24-34, 38-56 are rejected.
5. ☐ Claims _____ are objected to.
6. ☐ Claims _____ are subject to restriction or election requirement.
7. ☐ This application has been filed with informal drawings under 37 C.F.R. 1.85 which are acceptable for examination purposes.
8. ☐ Formal drawings are required in response to this Office action.
9. ☐ The corrected or substitute drawings have been received on _____. Under 37 C.F.R. 1.84 these drawings are ☐ acceptable. ☐ not acceptable (see explanation or Notice re Patent Drawing, PTO-948).
10. ☐ The proposed additional or substitute sheet(s) of drawings, filed on _____ has (have) been ☐ approved by the examiner. ☐ disapproved by the examiner (see explanation).
11. ☐ The proposed drawing correction, filed on _____, has been ☐ approved. ☐ disapproved (see explanation).
12. ☐ Acknowledgment is made of the claim for priority under U.S.C. 119. The certified copy has ☐ been received ☐ not been received ☐ been filed in parent application, serial no. _____; filed on _____.
13. ☐ Since this application appears to be in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under Ex parte Quayle, 1935 C.D. 11; 453 O.G. 213.
14. ☐ Other

EXAMINER'S ACTION

Claims 4-9, 12-14, 24-30, 46-52, and 55-56 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 4-9 are unclear as to how they relate to the sequences claimed in claim 1. Claim 1 is to a particular sequence and serotypic variants thereof, yet claims 4-9 are to much smaller sequences.

Claims 12-14 lack proper antecedant basis for a hybrid duplex molecule from claim 9.

Claim 24 is unclear as to what constitutes a "portion thereof" of the hap protein.

Claim 25 lacks proper antecedant basis for "process" from claim 20 and depends upon cancelled claim.

Claims 26-29 suffer the same defect as claim 25.

Claim 33 is unclear as to what is meant by a "portion of said DNA comprises the DNA sequence" of claim 1. Does applicant mean the E. coli comprises a plasmid containing the sequence of claim 1.

Claim 46 is unclear as to what constitutes a "portion thereof". The functional limitation of a "portion encoding a protein capable of binding retionic acid and functioning as a receptor" could be clearer.

Claim 55 is unclear as to what is meant by "a portion of said DNA comprises the DNA sequence of claim 38". Is the DNA on a plasmid?

Claims 19, 22-23 are provisionally rejected under the judicially created doctrine of obviousness type double patenting as being unpatentable over claims 1-14, 24-34, 38-56 are of copending application Serial No. 07/133,687. Although the conflicting claims are not identical, they are not patentably distinct from each other because both are drawn to DNA sequences corresponding to hap gene or vectors containing once the DNA had been isolated, its utility as a probe or for expression would have been obvious given importance of receptors in gene expression regulation and assays.

The obviousness type double patenting rejection is a judicially established doctrine based upon public policy and is primarily intended to prevent prolongation of the patent term by prohibiting claims in a second patent not patentably distinct from claims in a first patent. In re Vogel, 164 USPQ 619 (CCPA 1970). A timely filed terminal disclaimer in compliance with 37 CFR 1.321(b) would overcome an actual or provisional rejection on this ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.78(d).

The following is a quotation of 35 U.S.C. 103 which forms the basis for all obviousness rejections set forth in this Office action:

> A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.
>
> Subject matter developed by another person, which qualifies as prior art only under subsection (f) and (g) of section 102 of this title, shall not preclude patentability under this section where the subject matter and the claimed invention were, at the time the invention was made, owned by the same person or subject to an obligation of assignment to the same person.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103, the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of potential 35 U.S.C. 102(f) or (g) prior art under 35 U.S.C. 103.

Claims 1-14, 24-34, 38-56 are rejected under 35 U.S.C. 103 as being unpatentable over Dejean et al.

Dejean et al teach that HBV integrates into a human liver DNA sequence which bears a striking resemblance to an oncogene (v-erb-A) and the putative DNA binding domain of the human glycocorticoid receptor. They suggest that this gene is usually silent or transcribed at very low levels in normal cells, and is inappropriately expressed in hepatic carcinoma cells. They disclose the sequence corresponding to the integration in Fig. 2 and identify the presence of an open reading frame comprising the HBV integration. They indicate that this finding suggests that hormones may be implicated in HBV carcinogenesis since the gene is structurally similar to steroid receptor genes.

Weinberger et al teach the sequence of the human glucocorticoid receptor.

Green et al teach the sequence of the human estrogen receptor and its expression in transformed host cells.

It would have been prima facie obvious to have used the putative 147 basepair cellular exon in which HBV integration took place disclosed by Dejean et al as a probe to screen a human liver cDNA library for the en-

tire gene comprising this exon in view of its structural similarity to both the human glycocorticoid receptor taught by Weinberger et al and the human estrogen receptor taught by Green et al which would point to the possibility that this exon is from a DNA coding for a hormone receptor. Once the appropriate cDNAs had been identified by hybridization, it would have been routine to the skilled artisan to have sequenced said cDNAs and used as labelled probes to identify analogous receptor encoding nucleotides form other cDNA, genomic libraries, or from mRNA isolates. Once the cDNA had been identified, it further would have been obvious to have used it to express the corresponding protein by insertion into known expression vectors suitable for expression in E. coli such as disclosed by Green et al for the estrogen receptor since there would be an expectation the resulting protein could be used in ligant/receptor binding assays.

Any inquiry concerning this communication should be directed to Examiner Teskin at telephone number 703-557-5996.

Applicant is requested to submit a 1449 corresponding to the disclosure statement, paper #6. (Note that U.S. patent applications are not appropriate on 1449)

Teskin/th
7-23-90/7-30-90

Robin L Teskin
ROBIN L. TESKIN
PRIMARY EXAMINER
ART UNIT 185